DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
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November 4, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 04 – 04

Joseph M. Hogan
President and Chief Executive Officer
GE Medical Systems
3000 N. Grandview Boulevard
Waukesha, Wisconsin 53118

Dear Mr. Hogan:

On September 9 and 12, 2003, inspectors from the State of Mississippi [under contract with the U.S. Food and Drug Administration (FDA)] conducted a field test (#GI70353) of a certified diagnostic x-ray system at:

User Site: [redacted]

System Information: Room number: R&F 1
Control Manufacturer: General Electric
Control Model: 2289299
Control Serial: BRCWBH

Based on your submission of Form FDA-2579, #G142483, your firm assembled this system on June 9, 2003.

We tested this system to determine its compliance with portions of the Performance Standard for Diagnostic X-ray Equipment [Title 21, Code of Federal Regulations, Sections 1020.30-32 (21 C.F.R. 1020.30-32)]. Diagnostic x-ray equipment is a medical device as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act) (21 U.S.C. § 321(h)]. Our analysis of the field test data indicates that the system is not in compliance with the following item of the performance standard:

Class A Violation ***(conditions that pose a serious radiation hazard)***

During testing on September 9, 2003, x-ray production was possible when the primary protective barrier was not in position to intercept the x-ray beam as required by 21 C.F.R. § 1020.32(a).

Per your September 9, 2003, service record (#0260365963) your firm has reportedly adjusted the system to correct this hazard. In your response to this letter please provide additional detail so that we can determine if this serious hazard was assembler-based, manufacturer-based, or of user-based origin (see below). Please also provide an assessment if this hazard is related to this single unit, or has model-wide implications.

In addition to the above problem, we consider the compliance status of the following item to be suspect. Please verify the compliance status of this item when you correct the previously described problem:

The discrepancy between the actual vs. indicated field size, obtained by manual adjustment of the collimator was calculated to be, at 36" SID,
-3.2% in the along-table dimension
-2.9% in the across-table dimension

The x-ray performance standard, 21 C.F.R. § 1020.31(e)(3) requires that manual aperture adjustments to the collimator correspond to the actual x-ray field size dimensions, to within 2% of the SID.

We request that you, as the responsible assembler, immediately investigate the above-noted deviations in accordance with 21 C.F.R. Parts 1003 and 1004 as follows:

1) If you determine that the deviations and/or defects are caused by improper assembly or installation, the regulations require you to correct the non-compliance at no charge to the user by repairing the system, replacing it, or refunding the cost.

2) If you determine that the deviations and/or defects are caused by the factory-based manufacturer, the regulations require you to notify the manufacturer of the non-compliance and/or defect and send documentation of such notification to this office.

3) If you can establish that the system is compliant, that the alleged deviations and/or defects do not exist or do not relate to the safety of the product, or are directly attributable to user abuse or lack of maintenance, you may

submit such evidence in accordance with 21 C.F.R. § 1003.11(a)(3) within 15 working days of receipt of this letter.

Please report the results of your investigation and follow-up action to this office within 15 working days of the receipt of this letter. Your response should include the date that the corrective action was completed and copies of service records and/or other supportive documents. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. If you do not respond within 15 working days, the FDA may consider you to be in violation of the Act, Sections 538(a)(2) and 538(a)(4) of subchapter C—Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968).

Your response should be sent to X-ray Auditor Thomas W. Garvin, Food and Drug Administration, 2675 North Mayfair Road, Suite 200, Milwaukee, WI 53226-1305.

Any questions regarding the field test can be directed to Mr. Garvin at (414) 771-7167 ext. 12.

Sincerely,

/s/ W. Charles Becoat

W. Charles Becoat
Director
Minneapolis District

TWG/ccl

xc:

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